

REMARKS

In the Office Action, claims 5-22 are provisionally rejected under 35 U.S.C. § 101; and claims 1-22 are rejected under 35 U.S.C. § 103. Applicants believe that the rejections are improper based on at least the reasons as set forth below.

With respect to the provisional rejection of claims 5-22 under 35 U.S.C. § 101, Applicants believe the Patent Office has incorrectly asserted that claims 5-22 of the present application claim the same invention as that of claims 5-22 of co-pending application No. 09/206,063. Foremost, the Patent Office wrongly asserts that the subject matter as defined in claims 5-22 of the present application is drawn to methods of preparing a stabilized osmotic agent in support of the statutory double patenting rejection. Indeed, the Patent Office fails to give any patentable consideration to the preamble as defined in the claims. This is clearly improper.

Of course, the Court of Appeals for the Federal Circuit has held that “[i]n general, a preamble limits the claimed invention … if it is ‘necessary to give life, meaning and vitality’ to the claim.” *In re Cruciferous Sprout Litigation et al. v. Sunrise Farms et al.*, U.S.P.Q.2d 1202, 1204 (Fed. Cir. 2002) (quoting *Pitney Bowes Inc. v. Hewlett Packard Co.*, 51 U.S.P.Q.2d 1161, 1165) (Fed. Cir. 1999)). Further, “[c]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art may indicate that the preamble is a claimed limitation because the preamble is used to define the invention.” *Id.*

In this case, the specification and the examination process clearly support Applicants' position that the preamble language of claims 5-22 should be given patentable weight. Of the pending claims at issue, claims 5, 11 and 17 are the sole independent claims. Claim 5 relates to a method of administering an autoclavable osmotic agent to a subject in need thereof; and claims 11 and 17 relate to a method of administering a sterilizable osmotic agent to a subject in need thereof. The method of administering limitation as defined in claims 5-22 is clearly supported in the Specification, for example, on page 1 at lines 9-12, and see, generally, Summary of Invention. Further, Applicants have and continue to argue during the examination of the present application that the method of administering an autoclavable or sterilizable osmotic agent as defined by claims 5-22 is a distinguishable feature over the cited art. Therefore, Applicants believe that the preamble language relating to methods of administering osmotic agents as defined in claims 5-22 should be given patentable weight.

As such, clearly the subject matter as defined in claims 5-22 of the present application and claims 5-22 of co-pending patent application No. 09/206,063 do not define the same invention pursuant to 35 U.S.C. § 101. Again, claims 5-22 relate to methods of administering an autoclavable or sterilizable osmotic agent as previously discussed. In contrast, claims 5-22 of the co-pending application relate to methods of preparing a stabilized osmotic agent. Therefore, the requirements pursuant to 35 U.S.C. § 101 have been satisfied.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claims 1-4 were rejected under 35 U.S.C. § 103 as allegedly unpatentable over U.S. Patent No. 4,886,789 (“*Milner*”) and European Patent Document No. 0612528 (“*Bellini*”). The Patent Office again primarily relies on *Milner* and thus relies on *Bellini* to remedy the deficiencies of same.

Applicants believe that this rejection is improper. At the outset, the Patent Office has improperly relied on alleged and general disclosures in *Milner* to support the obviousness rejection. While *Milner* may generally disclose polymers that are linked by 1-4 alpha and 1-6 alpha-D-glycosidic chemical bonds, nowhere does *Milner* disclose or suggest the use of glucose polymers that are linked by bonds that include at least 85%, by number, alpha-1, 4 bonds as required by the claimed invention. Further, *Milner* fails to disclose the specific type of glucose polymer, namely, D-glucitol, gluconic acid or alkylglycoside with formulas as required by the claimed invention. Indeed, the primary focus of *Milner* relates to the use of glucose polymers as a substitute for dextrose. Thus, *Milner* fails to address the problem of the decomposition of glucose or glucose polymers during sterilization or autoclaving procedures in contrast to the present invention. Therefore, Applicants believe that *Milner*, on its own, is clearly deficient with respect to the claimed invention.

Further, Applicants do not believe that *Bellini* can be relied on solely to remedy the deficiencies of *Milner*. In this regard, the Patent Office merely relies on *Bellini* for its alleged teaching regarding the use of gluconic acid in a peritoneal dialysis solution. Thus, even if combinable, Applicants do not believe that one skilled in the art would be inclined to modify the cited art to arrive at the claimed invention. To do so would require hindsight reasoning and, of course, this would be clearly improper.

Based on at least these reasons, Applicants believe that the cited art fails to disclose or suggest the claimed invention. Therefore, Applicants believe that the cited art, even if combinable, fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, Claims 5-22 are rejected under 35 U.S.C. 103 as being unpatentable over SOLOMONS, Organic Chemistry, 2nd edition, 1976, p. 890 ("SOLOMONS") in combination with AMAN et al., Carbohydrates in Food, p. 195, 1996 ("AMAN") and U.S. Patent No. 3,974,034 ("HORN"). The Patent Office primarily relies on *SOLOMONS* and thus relies on the other cited art to remedy the deficiencies of *SOLOMONS*.

Applicants believe that this rejection is improper. Of the pending claims at issue, Claims 5, 11 and 17 are the sole independent claims. As previously discussed, Claim 5 relates to a method of administering an autoclavable osmotic agent to a subject in need thereof; and Claims 11 and 17 relate to a method of administering a sterilizable osmotic agent to a subject in need thereof. Claim 5 further recites that the osmotic agent is prepared by providing a solution of starch dissolved in water; and adding NaBH₄ to the starch solution to reduce the starch.

Claim 11 further recites that the osmotic agent is prepared by providing a solution of starch dissolved in water; providing a solution of NaOCl; and adding the NaOCl solution to the starch solution to oxidize the starch. Claim 17 recites that the osmotic agent is prepared by dissolving starch in an acid and an alcohol selected from the group consisting of methanol, butanol, and glycerol.

At the outset, Applicants believe that the Patent Office has improperly given little, if any patent consideration to the method of administering features as defined in the preamble of claims 5-22. Indeed, Applicants do not believe that the cited art makes reference to the word "osmotic agent," let alone to its administration thereof. Why then would one skilled in the art consider these references to disclose or even suggest the claimed invention. Moreover, Applicants respectfully submit that the present invention deals with a recognized problem in the art by providing methods for administering stabilized osmotic agents composed of icodextrins. If stabilized, the osmotic agent is autoclavable and thus sterilizable. In this regard, Applicants have uniquely discovered that autoclavable or sterilizable osmotic agents composed of icodextrins can be prepared such that they can be effectively administered to a subject in need.

Contrary to the Patent Office's position, Applicants respectfully question how the differences between the cited references and the claimed invention would otherwise be obvious when, for example, not one of the references deals with the issues involved with an osmotic agent, let alone the administration thereof; not one of the references deals with stabilizing an osmotic agent, let alone the administration thereof; not one of the references deals with the problems of a non-sterilizable osmotic agent that is heated; and not one of the references relates to a stabilized icodextrin that is autoclavable and thus sterilizable, let alone the administration thereof. Applicants respectfully question why would the art therefore suggest to anyone, let alone one skilled in the art, at the time of the claimed invention, to modify the references to provide a method of administering an autoclavable or sterilizable osmotic agent to a subject in need thereof. Therefore, Applicants believe that the cited art is clearly deficient with respect to the claimed invention.

Based on at least these noted differences between the cited art and the claimed invention, Applicants respectfully submit that the cited art, even if combinable, fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the rejection should be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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